

REMARKS

In response to the Office action dated December 20, 2010, Applicants have added new claims 18 and 19. Support for new claim 18 can be found, e.g., in paragraph [0029] of the specification. Support for new claim 19 can be found, e.g., in paragraph [0047] of the specification. No new matter has been introduced by the above amendments. Claims 1-7 and 17-19 are presented for examination. Claims 8-16 remain withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 1-7 and 17 are rejected under 35 U.S.C. §103(a) as obvious from Oishi et al., U.S. Patent No. 7,087,168 ("Oishi").

Independent claim 1 is discussed first. Claim 1 recites bundles containing a plurality of selectively permeable polysulfone-based hollow fiber membranes, each of which has an inner surface for contacting blood and an outer surface for contacting a dialyzing fluid. The content of a hydrophilic polymer (e.g., polyvinyl pyrrolidone) in the outer surface of a hollow fiber membrane is 25 to 50 mass %. Further, the bundles of claim 1 exhibit, among others, two features: (1) any of extracted solutions from ten fractions of said bundle, obtained by dividing said bundle at substantially regular intervals along the lengthwise direction, shows a maximum value of smaller than 0.10 in UV absorbance at a wavelength of 220 to 350 nm, with the proviso that said extracted solutions are obtained by the extraction method for tests regulated in the approval manufacturing standards for dialytic artificial kidney devices; and (2) the difference between the maximum and the minimum out of the maximum values of UV absorbance of the extracted solutions from the respective fractions is not larger than 0.05. According to the specification, controlling the content of the hydrophilic polymer in the outer surface of a membrane to 25-50 mass% can both improve the priming capacity of the membrane and inhibit the infiltration of endotoxins into the blood contact side of the membrane. *See, e.g.*, paragraphs [0033] and [0035]. Further, according to the specification, controlling the difference between the maximum and the minimum out of the maximum values of UV absorbance of the extracted solutions from the respective fractions to not larger than 0.05 can reduce the variation in the contents of the hydrophilic polymer in the outer surfaces of the hollow fiber membranes along

the lengthwise direction of the bundle and therefore resolve the partial sticking problems of hollow fiber membranes. *See, e.g.*, paragraphs [0046] and [0047].

Oishi discloses a membrane that includes a polysulfone-based polymer and polyvinyl pyrrolidone (PVP), in which the PVP content on the inner surface of the membrane is 30-45%. *See, e.g.*, column 6, lines 9-12. The Examiner asserts that "it would have been obvious to a routineer in the art at the time the invention was made to have the disclosed content of PVP on the outer surface, since it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art (MPEP 2144[.04] Section VI, Part A)." *See* the Office action, page 3, 2nd last paragraph. Applicants respectfully disagree.

MPEP 2144.04 VI.A quotes *In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) and states that "[p]rior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient." By contrast, Oishi cited in the Office action is clearly different from the prior art cited in *In re Gazda*. Specifically, unlike the prior art cited in *In re Gazda*, Oishi emphasizes that the PVP content of 30-45% on the inner surface of its membrane is critical to reduce blood clotting and the eluted amount of the PVP in the blood. *See* column 6, lines 18-26. It is completely silent on the PVP content on the outer surface of its membrane. In other words, the PVP content on the outer surface of Oishi's membrane is irrelevant to Oishi's invention. Thus, one skilled in the art, in view of Oishi, would have no reason to control the PVP content on the outer surface to 25-50 mass% as recited in claim 1. Indeed, there is simply nothing in Oishi that would have prompted one skilled in the art to control the PVP content on the outer surface of a membrane. Applicants submit that the Examiner's argument is a typical "**hindsight analysis**," which has been repeatedly disapproved by courts.

In addition, even assuming that one skilled in the art somehow were motivated to control the PVP content on the outer surface of Oishi's membrane (which Applicants do not concede), that person, in view of Oishi, would not know how to adjust the PVP content on the outer surface to 20-50 mass% as recited in claim 1. The present application teaches several methods of control the PVP content on the outer surface of the hollow fiber membrane. For example, the present application teaches that

“To control the content of the hydrophilic polymer on the outer surface of the hollow fiber membrane within the above specified range, for example, the ratio of the hydrophilic polymer to the hydrophobic polymer is controlled within the above specified range; or the hollow fiber membrane-manufacturing conditions are optimized. It is also an effective method to wash the hollow fiber membranes. The optimization of the hollow fiber membrane manufacturing conditions such as the humidity control of the air gap section at the exits of nozzles, drawing condition, the temperature of a coagulation bath, the composition ratio of a solvent to a non-solvent in a coagulating liquid, etc. is also effective.”

See paragraph [0036]. By contrast, as discussed above, Oishi is completely silent on controlling the PVP content on the outer surface of its membrane, let alone doing so by any of the methods described in the quoted passage above. In addition, in view of the above teachings in the specification, it would have been apparent to one skilled in the art that controlling the PVP content on the outer surface of a membrane is not a simple reversal of the inner surface to the outer surface, as asserted by the Examiner. Indeed, the Examiner's proposed reversal may result in a membrane having a PVP content on the inner surface outside the range of 30-45% (when the PVP content of the outer surface is outside the range of 30-45% before the reversal), which would render the resultant membrane unsatisfactory for its intended purpose. The Examiner is reminded that “THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” *See* MPEP 2143.01 V.

Thus, Oishi does not disclose or render obvious that the content of its hydrophilic polymer in the outer surface of a hollow fiber membrane is 25 to 50 mass %, a limitation recited in claim 1. Further, Oishi does not disclose or render obvious that the difference between the maximum and the minimum out of the maximum values of UV absorbance of the extracted solutions from the respective fractions is not larger than 0.05, another limitation recited in claim 1.

For at least the reasons set forth above, claim 1 would not have been obvious from Oishi. Since claims 2-7 and 17 depend from claim 1, they also would not have been obvious from this reference.

Double patenting rejection

Claims 1 and 3-6 are rejected under the non-statutory obviousness-type double patenting as unpatentable over claims 1, 2, and 5-7 of U.S. Patent No. 7,442,302. Applicants ask that this rejection be held in abeyance until the pending claims are otherwise in condition for allowance.

New claims

Applicants submit that new claims 18 and 19 are patentable of Oishi.

Claims 18 and 19 depend from claim 1. As discussed above, claim 1 is patentable over Oishi. So are claims 18 and 19.

In addition, claims 18 and 19 are patentable over Oishi on additional, independent grounds.

Claim 18 recites that the mass ratio of the hydrophilic polymer to the polysulfone-based resin is 1 to 8 mass %. By contrast, Oishi discloses that the mixed ratio of the PVP and the polysulfone-based polymer in its membrane is 10-27 wt%. See column 8, line 66 to column 9, line 2. It also discloses that “[i]f the mixed ratio is below 10 wt%, the viscosity of the raw material polymer solution decreases and it is difficult to obtain a membrane with a sponge-like structure.” See column 9, lines 4-7; emphasis added. Oishi does not disclose or render obvious a membrane in which the mass ratio of the hydrophilic polymer to the polysulfone-based resin is 1 to 8 mass %, as recited in claim 18. Indeed, to the extent that Oishi teaches that using a mixed ratio of the PVP and the polysulfone-based polymer below 10 wt% would not obtain a membrane with the desired sponge-like structure, it **teaches** one skilled in the art **away** from the mass ratio of 1 to 8 mass % recited in claim 18. Thus, claim 18 is patentable over Oishi on this additional, independent ground.

Claim 19 recites that the extracted solutions show a maximum value of at least 0.05 in UV absorbance at a wavelength of 220 to 350 nm. By contrast, Oishi discloses that “the absorbance of elution test solution of the membrane of the present invention is less than 0.04.” See column 5, lines 41-42; emphasis added. Oishi does not disclose or render obvious any extracted solutions showing a maximum value of at least 0.05 in UV absorbance at a wavelength of 220 to 350 nm, as recited in claim 19. Thus, claim 19 is patentable over Oishi on this additional, independent ground.

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Conclusion

Applicants submit that this application is now in condition for allowance and request favorable action.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; and (b) made arguments for the patentability of some claims does not mean that there are no other good reasons for the patentability of those claims and other claims.

The \$490.00 fee for the Petition for Two-Month Extension of Time is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0004US1.

Respectfully submitted,

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